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PTO/SB/21 (05-03)

Approved for use through 04/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

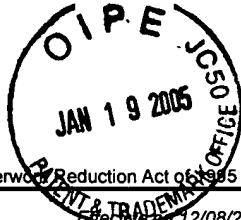
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM (to be used for all correspondence after initial filing)		Application Number	09/917,222	
		Filing Date	July 27, 2001	
		First Named Inventor	GRANOFF, DAN M.	
		Group Art Unit	1645	
		Examiner Name	ZEMAN, ROBERT A.	
Total Number of Pages in This Submission		14	Attorney Docket Number	CHOR-001
ENCLOSURES (check all that apply)				
<input checked="" type="checkbox"/> Fee Transmittal Form In Duplicate <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Documents <input type="checkbox"/> Response to Missing Parts/ Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53		<input type="checkbox"/> Assignment Papers (for an Application) <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s)		<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input checked="" type="checkbox"/> REQUEST UNDER 37 C.F.R. §1.705(b) FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Exhibit A: Copy of the postcard stamped by the OIPE showing the application filing date Exhibit B: Copy of the Restriction Requirement Postcard
Remarks				
SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT				
Signing Attorney/Agent (Reg. No.)	Edward J. Baba, 52,581 BOZICEVIC, FIELD & FRANCIS, LLP			
Signature				
Date	January 19, 2005			

EXPRESS MAIL LABEL NO. EV 519869335 US

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



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FEE TRANSMITTAL For FY 2005		Complete if Known	
		Application Number	09/917,222
		Filing Date	July 27, 2001
		First Named Inventor	GRANOFF, DAN M.
		Examiner Name	ZEMAN, ROBERT A.
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27		Art Unit	1645
TOTAL AMOUNT OF PAYMENT		Attorney Docket No.	CHOR-001
(\$) 200.00			

METHOD OF PAYMENT (check all that apply)

- ☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____
- ☒ Deposit Account Deposit Account Number: **50-0815** Deposit Account Name: **Bozicevic, Field and Francis LLP**
For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)
- ☒ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, except for the filing fee
- ☒ Charge any additional fee(s) or underpayments of fee(s) ☒ Credit any overpayments
under 37 CFR 1.16 and 1.17

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

FEE CALCULATION**1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 or, for Reissues, each claim over 20 and more than in the original patent	50	25
Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent	200	100
Multiple dependent claims	360	180
Total Claims	Extra Claims	Fee (\$)
- 20 or HP = _____ x _____ = _____		
HP = highest number of total claims paid for, if greater than 20		
Indep. Claims	Extra Claims	Fee (\$)
- 3 or HP = _____ x _____ = _____		
HP = highest number of independent claims paid for, if greater than 3		

3. APPLICATION SIZE FEE


If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
- 100 = _____ / 50 = _____ (round up to a whole number) x _____ = _____				

4. OTHER FEE(S)

Non-English Specification, \$130 fee (no small entity discount)

Other: **Request Fee Under 37 C.F.R. §1.18(e) and (2)****Fee Paid (\$)****\$ 200.00****SUBMITTED BY**

Signature		Registration No. (Attorney/Agent) 52,581	Telephone (650) 327-3400
Name (Print/Type)	Edward J. Baba	Date 01/19/2005	

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



EXPRESS MAIL NO. EV 519869335 US

**REQUEST UNDER
37 C.F.R. §1.705(b) FOR
RECONSIDERATION OF
PATENT TERM ADJUSTMENT**

Address to:
ISSUE FEE
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313

Attorney Docket No.	CHOR-001
Confirmation No.	9605
First Named Inventor	Dan M. Granoff
Application Number	09/917,222
Filing Date	July 27, 2001
Group Art Unit	1645
Examiner Name	Zeman, Robert A.

Title: VACCINES FOR BROAD SPECTRUM
PROTECTION AGAINST DISEASES
CAUSED BY NEISSERIA
MENINGITIDIS

Sir:

Under 37 C.F.R. §1.705(b), Applicant hereby requests reconsideration of the patent term adjustment indicated in the notice of allowance mailed on December 21, 2004 for the above-identified patent application and hereby petitions for reinstatement of **one hundred forty-seven (147)** days for which the patent term adjustment was reduced.

Provided herewith is:

- (1) the fee of \$200.00 as set forth in 37 C.F.R. §1.18(e); and
- (2) a statement of the facts involved, as follows:

- (i) The correct patent term adjustment should be 320 days under 37 C.F.R. §1.702(a);

- (ii) The relevant dates for which an adjustment is sought is provided as follows:

In the notice of allowance mailed on December 21, 2004, it was indicated that the patent term adjustment to date for this application is 173 days. According to the patent term adjustment history, the patent term was adjusted 258 days due to the Patent Office's delay in examination. Additionally, the patent term adjustment was reduced by 85 days for apparent delay by the Applicant.

Upon a telephone discussion with the Office of Patent Legal Administration at the Patent Office, Applicant's attorney confirmed that the determination of patent term adjustment of 258 days due to Patent Office's delay in examination was incorrect.

Under 37 C.F.R. 1.702(a)(1) "the term of an original patent shall be adjusted if the issuance of the patent was delayed due to failure of the office to mail at least one of a notification

under 35 U.S.C. §132 or a notice of allowance under 35 U.S.C. §151 not later than fourteen months after the date on which the application was filed.” Accordingly, under 37 CFR §1.703 (a)(1) “the period of adjustment under § 1.702(a) is the sum of ... the number of days, if any, in the period **beginning on the day after the date that is fourteen months after the date on which the application was filed** under 35 U.S.C. §111(a) or fulfilled the requirements of 35 U.S.C. §371 **and ending on the date of mailing of either an action under 35 U.S.C. §132, or a notice of allowance under 35 U.S.C. §151**, whichever occurs first.”

The present application was filed on July 27, 2001 (Exhibit A – Copy of the postcard stamped by the OIPE showing the application filing date). The date of mailing of either an action under 35 U.S.C. §132, or a notice of allowance under 35 U.S.C. §151, was November 7, 2003 (Exhibit B – Copy of the Restriction Requirement). The date that is fourteen months after the date on which the application was filed is September 28, 2002. The number of days beginning on September 28, 2002, and ending on November 7, 2003, is 405 days not 258 days. Therefore, the applicants are owed 147 days.

Applicant respectfully submits that the determination of Patent Office delay of 258 days is incorrect as the Office did not issue an action under 35 U.S.C. §132 until November 7, 2003. Therefore, the patent term should be adjusted a total of 405 days due to the Patent Office’s delay in examination, not 258 days. As such, the patent term adjustment to date for this application should be 320 days, not 173 days.

Thus, the Applicant is owed the patent term adjustment of 147 days without reduction.

(iii) The subject application and patent issuing therefrom is not subject to a terminal disclaimer.

(iv) There are no circumstances constituting a failure by the Applicant to engage in reasonable efforts to conclude processing or examination of such application as set forth in 37 C.F.R. §1.704.

Applicant respectfully requests that the subject application for patent term adjustment of 147 days be granted.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number CHOR-001.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: Jan. 19, 2005

By: 

Edward J. Baba
Registration No. 52,581

Enclosures:

Exhibit A: Copy of the postcard stamped by the OIPE showing the application filing date
Exhibit B: Copy of the Restriction Requirement

BOZICEVIC, FIELD & FRANCIS LLP
1900 University Avenue, Suite 200
East Palo Alto, California 94303
Telephone: (650) 327-3400
Facsimile: (650) 327-3231

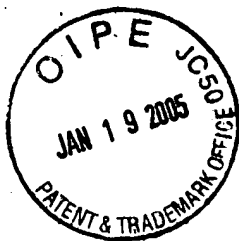


Exhibit A

Atty. Docket No.: CHOR-001
Patent No.: Unassigned
Atty./Sec.: CLF/sg

EL 923 479 893 US
Date Mailed: July 27, 2001
Filing Date: Herwith
Inventor(s): Dan Granoff et al.

Title: "Vaccines for Broad Spectrum Protection Against Diseases
Caused by Neisseria Meningitidis"

Enclosure(s):

- ❖ Non Fee Utility Application (2 pages)
- ❖ Application Data Sheet (2 pages)
- ❖ Specification Claims and Abstract (78 pages)
- ❖ Drawings (23 pages)
- ❖ Return Postcard



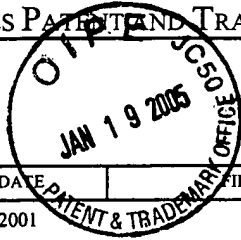
Please Acknowledge receipt of enclosures by PTO date-stamping
postcard and returning to sender via US Mail.



UNITED STATES PATENT AND TRADEMARK OFFICE

Exhibit B

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov



APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,222	07/27/2001	Dan M. Granoff	CHOR-001	9605

24353 7590 11/07/2003

BOZICEVIC, FIELD & FRANCIS LLP
200 MIDDLEFIELD RD
SUITE 200
MENLO PARK, CA 94025

EXAMINER

ZEMAN, ROBERT A

ART UNIT PAPER NUMBER

1645

DATE MAILED: 11/07/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

KB

11/14/03

RR

12/07/03

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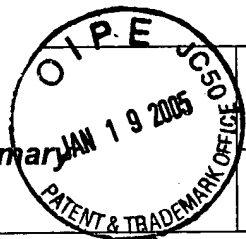
05/07/04

RECEIVED

NOV 12 2003

Bozicevic, Field, & Francis

Office Action Summary



Application No.

09/917,222

Applicant(s)

GRANOFF ET AL.

Examiner

Robert A. Zeman

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-15 and 20-27, drawn to methods of eliciting protective immunity against *Neisseria meningitidis* utilizing preparations of microvesicles, outer membrane vesicles and combinations thereof derived from *Neisseria meningitidis*, classified in class 424, subclass 250.1.
- II. Claims 16-27 and 39, drawn to methods of eliciting protective immunity against *Neisseria meningitidis* utilizing antigens derived from *Neisseria meningitidis*, classified in class 424, subclass 250.1.
- III. Claim 28, drawn to methods of determining antigenic epitopes that elicit protective immunity against *Neisseria meningitidis*, classified in class 436, subclass 547.
- IV. Claims 29-33, drawn to compositions comprising microvesicles, outer membrane vesicles and combinations thereof derived from *Neisseria meningitidis*, classified in class 530, subclass 350.
- VI. Claims 34-38, drawn to compositions comprising antigens derived from *Neisseria meningitidis*, classified in class 530, subclass 403.

The inventions are distinct, each from the other because of the following reasons:

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Inventions III and IV are separate and distinct from each other, as they comprise differing biochemical and immunological entities having differing properties and uses. Each invention constitutes a patentably distinct antigenic composition.

Inventions I and II are each separate and distinct from each other as they are drawn to differing methods utilizing differing reagents and having different steps.

Inventions III and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compositions of Invention III can be used in antibody purification methods.

Inventions IV and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compositions of Invention IV can be used in antibody purification methods.

Invention II is separate and distinct from Invention III, as the compositions of Invention III cannot be used in the methods of Invention II.

Invention II is separate and distinct from Invention IV, as the compositions of Invention III cannot be used in the methods of Invention I.

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Because these inventions are distinct for the reasons given above and the search required for the various groups would not be coextensive in scope, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection

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are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined.

See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues.

See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991.

The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

Art Unit: 1645

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read "Robert A. Zeman". The signature is fluid and cursive, with a long horizontal stroke at the end.

Robert A. Zeman
November 4, 2003